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15N1 0007

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**NOTICE OF ALLOWANCE  
AND ISSUE FEE DUE**

☐ Note attached communication from the Examiner

☐ This notice is issued in view of applicant's communication filed

SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
01/21/96	09/20/95	017	HANCOCK, J.	03/07/96
First Named Applicant				
CHARLES T.				

TITLE OF  
INVENTION

MULTIPLEX GENOMIC DNA AMPLIFICATION FOR DETECTION OF TUMORS

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1255000	425-006.000	054	UTILITY	YES	400.00	06/07/96

**THE APPLICATION IDENTIFIES ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.  
PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS  
APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

I. Review the SMALL ENTITY Status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the patent and Trademark Office of the change in status, or
- B. If the Status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, pay of 1/2 the FEE DUE shown above.

II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.

III. All communications regarding this application must give series code (or filing date), serial number and batch number. Please direct all communication prior to issuance to Box ISSUE FEE unless advised to contrary.

**IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/315,673	09/30/94	CASKEY	C D5050000

MARSCHEL, EXAMINER

18N1/0307

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ART UNIT	PAPER NUMBER
1807	38

DATE MAILED: 03/07/96

### NOTICE OF ALLOWABILITY

#### PART I.

- ☒ This communication is responsive to 10/4/95
- ☒ All the claims being allowable. PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice Of Allowance And Issue Fee Due or other appropriate communication will be sent in due course.
- ☒ The allowed claims are 1-8 and 18-24; renumbered as 1-15, respectively
- ☐ The drawings filed on \_\_\_\_\_ are acceptable.
- ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has [ ] been received. [ ] not been received. [ ] been filed in parent application Serial No. \_\_\_\_\_, filed on \_\_\_\_\_
- ☒ Note the attached Examiner's Amendment.
- ☐ Note the attached Examiner Interview Summary Record, PTOL-413.
- ☒ Note the attached Examiner's Statement of Reasons for Allowance.
- ☒ Note the attached NOTICE OF REFERENCES CITED, PTO-892.
- ☐ Note the attached INFORMATION DISCLOSURE CITATION, PTO-1449.

#### PART II.

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" indicated on this form. Failure to timely comply will result in the ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

- ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
- ☒ APPLICANT MUST MAKE THE DRAWING CHANGES INDICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE OF THIS PAPER.
  - ☒ Drawing informalities are indicated on the NOTICE RE PATENT DRAWINGS, PTO-948, attached ~~to~~ to Paper No. 3. CORRECTION IS REQUIRED.
  - ☐ The proposed drawing correction filed on \_\_\_\_\_ has been approved by the examiner. CORRECTION IS REQUIRED.
  - ☐ Approved drawing corrections are described by the examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS REQUIRED.
  - ☒ Formal drawings are now REQUIRED. See attached reference to the MPEP regarding photographs.

Any response to this letter should include in the upper right hand corner, the following information from the NOTICE OF ALLOWANCE AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE NOTICE OF ALLOWANCE, AND SERIAL NUMBER.

#### Attachments:

- ☒ Examiner's Amendment
- ☐ Examiner Interview Summary Record, PTOL-413
- ☒ Reasons for Allowance
- ☒ Notice of References Cited, PTO-892
- ☐ Information Disclosure Citation, PTO-1449

- ☐ Notice of Informal Application, PTO-152
- ☐ Notice re Patent Drawings, PTO-948
- ☐ Listing of Bonded Draftsmen
- ☐ Other

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

In the claims:

This application is in condition for allowance except for the presence of claims 9-17 which have been nonelected without traverse as noted in the office action, mailed . Accordingly, claims 9-17 have been cancelled.

The following is an Examiner's Statement of Reasons for Allowance:

The instant invention is directed to target nucleic acid detection after PCR amplification wherein 3 or more primer sets, each directed to separate targets are utilized. The amending of the claims to accurately correspond to temperature ranges in the examples combined with the Declaration of Julian Gordon, Ph.D., as well as the striking similarity of melt temperature values in Table 1 are persuasive to overcome the rejection based on NEW MATTER. The closest prior art of record is that of Kogan et al. taken in view of Koenig et al.(1987) or Koenig et al.(1988) for certain dependent claims. The basic reference by Kogan et al. discloses multiple primer sets usage in PCR detection methods but also indicates some concern regarding specificity due to unexpected PCR products. This concern suggests significant doubt

regarding a reasonable expectation of success using three or more primer pairs in a PCR reaction and therefore supports that Kogan et al. suggests an obvious to try situation and therefore also supporting the allowability of the instant claims over Kogan et al.

Caskey et al. (EP 0,364,255) is cited on the enclosed PTO Form 892 as being interest as also disclosing the instant invention but after the instant filing date.

Photographic Drawings:

It is noted that formal drawings have been submitted. Since these drawings include photographs, applicants are hereby informed that a petition must be submitted and approved to permit the printing of photographic drawings. See the M.P.E.P. § 608.02, last full paragraph in the first column, at page 600-72 of Rev. 1, Sept. 1995.

Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 305-3014 or (703) 308-4227.

Serial No. 08/315,673

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Art Unit: 1807

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

AM A. MARSCHEL, Ph.D.  
March 4, 1996



W. GARY JONES  
SUPERVISORY PATENT EXAMINER  
GROUP 1800

3/4/96